K02 2940

510(k) Summary
In-Vision View with Measurements Module
Intelligent Images S.r.l.

OCT 11 2002

510 (k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21 CFR 807.92(a).

807.92(a)(1)

Submitter Information

Intelligent Images S.r.l.
12/3 Corso Galliera
16142 Genova, ITALY

Phone: +39 0105299309
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Contact Person: Maria Rosa Bellisario
Date: August 30, 2002

807.92(a)(2)

Device Name

Trade Name: In-Vision View with Measurements Module

Common Name: In-Vision View

Classification Name(s): System, Image Processing

Classification Number: LLZ

807.92(a)(3)

Predicate Device(s)

Manufacturer: MEDIS MEDICAL IMAGING SYSTEMS, B.V.
POORTGEBOUW RIJNSBURGERWEG 10
LEIDEN, NL 2333 AA
Tradename: QCU ANALYTICAL SOFTWARE PACKAGE
510(k) Number: K011582

Additional substantial equivalence information is provide in the following substantial equivalence comparison table.

807.92(a)(4)

Device Description

In-Vision View with Measurements Module is a software device intended to be used by qualified medical professionals, after proper installation on an appropriate hardware platform, for retrieving, viewing, and processing medical IVUS images stored using the JOMED In-Vision Gold or JOMED In-Vision Plus's CDR storage drive.

In-Vision View with Measurements Module provides an effective solution for physicians and interventional labs to review JOMED's In-Vision Gold digital IVUS DICOM video loops on a desktop PC or notebook. In addition, video loops and still frames can be exported to PowerPoint presentations for conferences, in-hospital training and lectures.

510(k) Summary
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807.92(a)(5)

Intended Use(s)

In-Vision View with Measurements Module is a software device intended to be used by qualified medical professionals, after proper installation on an appropriate hardware platform, for retrieving, viewing, and processing medical IVUS images stored using the JOMED In-Vision Gold or JOMED In-Vision Plus's CDR storage drive.

In-Vision View with Measurements Module supports JOMED DICOM files only. The software will not read DICOM images or loops stored using any other manufacturers' system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Mr. Maurizio Piaggio
President
Intelligent Images, S.r.l.
12/3 Corso Galliera
Genova, Genova
I-16142 ITALY

Re: K022940
Trade/Device Name: In-Vision View with Measurements Module
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 30, 2002
Received: September 4, 2002

Dear Mr. Piaggio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Intelligent Images S.r.l.

510(k) Number (if known): K02 2940

Device Name: In-Vision View with Measurements Module

Indications For Use:

In-Vision View with Measurements Module is a software device intended to be used by qualified medical professionals, after proper installation on an appropriate hardware platform, for retrieving, viewing, and processing medical IVUS images stored using the JOMED In-Vision Gold or JOMED In-Vision Plus's CDR storage drive.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use _____
(Per 21 CFR 801.109)

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022940

(Per 21 CFR 801.109)